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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,952	06/23/2003	Karl A. Jagger	1001.2192101	7910
11050 7590 06/12/2012 SEAGER, TUFTE & WICKHEM, LLC 1221 Nicollet Avenue Suite 800 Minneapolis, MN 55403				
EXAMINER				
SONNETT, KATHLEEN C				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
06/12/2012		PAPER		

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KARL A. JAGGER, LINDA S. CHRISTENSON, TODD ROWE,
STANLEY NORDIN, DANIEL NYGAARD, RANDALL J. BEYREIS,
and JON LIVINGSTON

Appeal 2011-004375
Application 10/601,952
Technology Center 3700

Before TONI R. SCHEINER, ERIC GRIMES, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of making a stent deployment system, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification discloses a balloon catheter stent deployment system in which a stent is mounted around the middle portion of a balloon

(Spec. 3: 13-14) and the “proximal section of the balloon has an uninflated initial outer diameter greater than the initial outer diameter of the stent” (*id.* at 3: 20-22). “This larger diameter of the proximal section of the balloon can protect the distal end of the stent from frictional forces in the event the balloon catheter needs to be withdrawn during a procedure” (*id.* at 3: 22-24) and “can also provide a centering action for the balloon and stent as the balloon catheter is advanced” (*id.* at 3: 25-26).

Claims 9-20 are on appeal. Claim 9 is the only independent claim and is directed to a method of making a balloon catheter stent deployment system that begins with the step of:

providing a balloon catheter comprising

an inner tubular shaft disposed within an outer tubular shaft, the inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and

an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof . . .

(Claim 9.) The complete text of claim 9 is reproduced in the Claims Appendix of the Appeal Brief (pages 16-17).

The Examiner has rejected claims 9 and 13 under 35 U.S.C. § 103(a) as obvious based on the method discussed as “prior art” in Shortt,¹ combined with Morales² and Hanson³ (Answer 3). The Examiner has also rejected claims 9 and 18 under 35 U.S.C. § 103(a) as obvious based on the method

¹ Shortt, US 6,948,223 B2, issued Sept. 27, 2005.

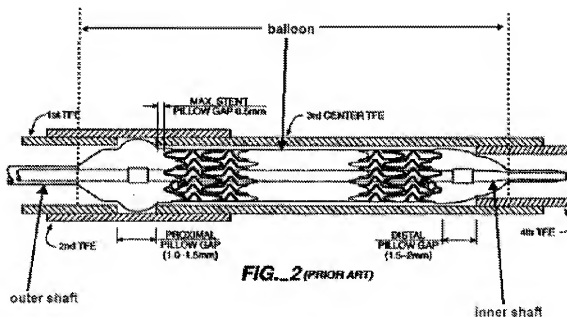
² Morales, US 5,920,975, issued July 13, 1999.

³ Hanson et al., US 5,893,868, issued Apr. 13, 1999.

disclosed by Shortt as its invention, combined with Morales and Hanson (Answer 6).

The Examiner finds that Shortt's discussion of a prior art method meets most of the limitations of claim 9, including the "providing" step quoted above (Answer 3-4). The Examiner relies on Morales for the step in claim 9 of crimping a stent after it is placed over a balloon (*id.* at 4-5) and relies on Hanson for the limitation of maintaining the diameter of the distal section of the balloon no larger than the diameter of the stent (*id.* at 5).

With regard to the balloon catheter's inner and outer tubular shafts, and attachment of the balloon to them, the Examiner provided an annotated version (reproduced below) of Shortt's Figure 2:



(Answer 14.) The figure is annotated to identify the part of the balloon proximal to the proximal pillow as the "outer shaft," the part of the balloon between and including the proximal and distal pillows as the "balloon," and the central shaft as the "inner shaft."

The Examiner also finds that the method disclosed by Shortt as its invention meets the same limitations that are met by the “prior art” method discussed by Shortt (Answer 6-7). The Examiner finds that the balloon catheter required by the claims is shown in Shortt’s Figure 7 (*id.* at 6).

Shortt’s Figure 7a is shown below:

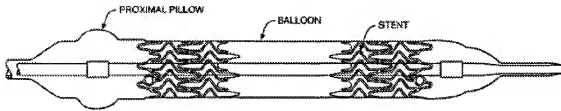


FIG. 7a

The figure shows “a delivery system with a standard stent profile” (Shortt, col. 5, ll. 9-10). Figures 7b and 7c are similar but show the balloon tapered (Figure 7b) or with a smaller diameter distal to the proximal pillow (Figure 7c).

Appellants argue that Shortt “does not teach ‘an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof,’” as required by the claims (Reply Br. 4). That is, “[i]n Shortt, the balloon is part of the outer shaft. Thus, the distal end of the outer shaft is distal the balloon, as illustrated in Figure 2 or Figures 7a-c of Shortt. It is the distal end of the outer shaft that is attached to the distal end of the inner shaft.” (*Id.*)

Appellants argue that “[o]ne cannot simply assert that the outer shaft ends proximal the balloon, when Shortt clearly shows the outer shaft extending distal of the balloon” (*id.* at 5).

We agree with Appellants that the Examiner has not persuasively shown that either the “prior art” method discussed by Shortt or Shortt’s

inventive method itself would have made obvious a method that includes providing the balloon catheter required by claim 9. In both cases, the configuration of the shaft, balloon, and stent are the same. And in both cases, the configuration includes only a single shaft, not an inner shaft and outer shaft as required by the claims on appeal.

Although the Examiner's annotated drawing indicates that the "outer shaft" of Shortt's device is the portion of the balloon proximal to the proximal pillow, that designation appears to be arbitrary. We agree with Appellants that, even if the uninflated balloon surrounding the central shaft is interpreted as the "outer shaft" required by the claims, then the outer shaft ends at the distal end of the device, distal to the balloon and co-terminal with the end of the (inner) shaft, as shown in Figures 2 and 7a-c. The Examiner therefore has not shown that Shortt discloses or would have made obvious a "balloon catheter comprising . . . an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof," as required by the claims on appeal.

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

The Examiner has not persuasively shown that either the "prior art" or inventive method disclosed by Shortt would have made obvious a method that includes the "providing" step required by the claims on appeal. The Examiner has not pointed to any disclosure in Morales or Hanson that would remedy this deficiency. Nor has the Examiner identified any disclosure in any of the additional references cited in the rejections applied to dependent

claims 10-12, 14-17, 19 and 20 (Answer 5-6 and 8-13) that would make up for the deficiency in Shortt. We therefore reverse all of the rejections on appeal.

REVERSED

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